

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

*Meeting of the Arthritis Advisory Committee (AAC)*

**November 16, 2010**

*Marriott Inn and Conference Center  
University of Maryland University College (UMUC)  
Adelphi, Maryland*

**DRAFT AGENDA**

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*The committee will discuss biologic license application (BLA) 125370, belimumab, proposed trade name BENLYSTA, sponsored by Human Genome Sciences, for the proposed indication of reducing disease activity in adult patients with active, autoantibody-positive systemic lupus erythematosus (SLE).*

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| 8:00 a.m.  | Call to Order<br>Introduction of Committee   | <b>Kathleen O'Neil, M.D.</b><br>Chair, AAC  |
|            | Conflict of Interest Statement   | <b>Yvette Waples, Pharm.D.</b><br>Acting Designated Federal Official  |
| 8:10 a.m.  | Opening Remarks  | <b>Badrul Chowdhury, M.D., Ph.D.</b><br>Director, Division of Pulmonary, Allergy &<br>Rheumatology Products<br>CDER/FDA |
| 8:25 a.m.  | <b>Sponsor Presentations</b><br><br>Introduction<br><br>Systemic Lupus Erythematosus:<br>Unmet Medical Need<br><br>Mechanism of Action:<br>BLyS and Belimumab<br><br>Efficacy<br><br>Safety<br><br>Risk Management<br><br>Clinical Perspective |   |
| 9:55 a.m.  | Clarifying Questions for Sponsor Presenters  |   |
| 10:15 a.m. | Break  |   |
| 10:30 a.m. | <b>FDA Presentations</b><br><br>Efficacy and Safety Considerations<br><br>Statistical Considerations   |   |

11:45 a.m. Clarifying Questions for FDA Presenters

12:00 p.m. Lunch Break

1:00 p.m. Open Public Hearing

2:30 p.m. Charge to the Committee

2:35 p.m. Committee Discussion

3:30 p.m. Questions to the Committee

5:00 p.m. Adjournment

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